

REMARKS

Claims 1-12 are pending and presented for examination in connection with the subject application. Claims 1 and 2 are in independent form.

Applicants have hereinabove amended claims 1 and 2 to place the claims in better form for examination, without narrowing the scope of the claimed invention. Applicants maintain that no new matter is presented by this amendment. Accordingly, Applicants respectfully request that this Amendment be entered.

Rejection under 35 U.S.C. §112, second paragraph

In section 4 of the December 30, 2002 Office Action, claims 1-12 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

The Examiner stated that it remains the Examiner's position that the claim is indefinite for the reasons of record, as set forth in (section 3 of) Paper No. 7, mailed July 15, 2002.

The Examiner also stated that additionally Applicants' argument in support of the indefinite claim language is itself indefinite in that the argument comprised terms such as "to include". The Examiner further stated that it is clear that no metes and bounds have been defined, thus, the rejection is maintained.

As an initial matter, it appears that the rejection of claims 1-12 has been maintain based on recitation of "dendritic cell culture medium" in claim 7.

Applicants respectfully point out that claim 7 depends from claim 1, and only claim 8 depends from claim 7. Since none of the claims other than claim 7 recite "dendritic cell culture medium",

it is improper to reject claims 1-6 and 9-12 on the basis of recitation of "dendritic cell culture medium" in claim 7.

Furthermore, the rejection appears to be based on the term being too broad. However, as MPEP §2173.04 points out: "Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph."

As pointed out in MPEP §2173.02, the definiteness issue is "not whether more suitable language or modes of expression are available. ... Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire."

Since the application adequately describes an exemplary method of preparing dendritic cell culture medium (see, for example, page 8, lines 12-16), Applicants respectfully submit that claim 7 (as well as claim 8 which depends from claim 7) sets out and circumscribes the claimed subject matter with a reasonable degree of particularity and distinctness.

Accordingly, Applicants respectfully requests that the Examiner reconsider and withdraw the rejection of claims 1-12 under 35 U.S.C. §112, second paragraph.

Rejection under 35 U.S.C. §112, first paragraph

In Section 6 of the January 30, 2003 Office Action, claims 1-12 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the

application was filed, had possession of the claimed invention.

The Examiner stated that it remains his position that the specification says what it says "One requirement of blood mononuclear cell (MNC) products suitable for DC culture is collection of a maximum number of monocytes and monocyte precursors with a minimum number of red blood cells, lymphocytes and platelets. The Examiner also stated that this may be accomplished by pheresing donors on an apheresis system (e.g., Spectra, COBE BCT, Lakewood, CO) using a mononuclear cell program." The Examiner further stated that this "requirement" is not part of the claimed invention.

The Examiner stated that it remains the Examiner's position that, as none of Applicants' "exemplary periods of incubation" are recited in the claims, Applicants are arguing an unclaimed limitation and the "reproducible" method of the claims is not enabled.

The Examiner stated that it remains his position that the claims must include the steps essential to delineate the claimed invention. The Examiner also stated that Applicants' arguments regarding steps that could be performed or might be performed, or reagents that could be used or might be used, are insufficient to enable the claimed invention.

The Examiner stated that it remains his position that the use of microcarrier beads comprises a primary element of the invention of the instant claims and as such, some specific description of their use in the claimed method must be recited in the claims to provide an enabled invention.

Applicants have hereinabove amended claims 1 and 2 to place the claims in better form for examination. Applicants maintain that the claimed invention as set forth in the amended claims is fully

supported by the specification.

The claims appear to be rejected as nonenabled because specific periods of incubation are not recited in the claims. The December 30, 2002 Office Action does not address the remarks in Applicants' October 15, 2002 response because, according to the Office Action, Applicants' remarks were directed to information in the specification which is not recited in the claims.

Applicants maintain that it is an error to ignore the disclosure in the specification, in an enablement analysis. Applicants respectfully direct the Examiner's attention to MPEP §2164.08 which states that for an enablement analysis one "does not look to the claims but to the specification to find out how to practice the claimed invention."

As pointed out in Applicants' October 15, 2002 response, exemplary periods of incubation are provided in the application (at, for example, page 9, line 24 through page 10, line 5). One of ordinary skill in the art with the guidance of the application can of course determine, without undue experimentation, other suitable periods of incubation, depending on, for example, the size of the microcarrier beads, the container volume, the culture volume, etc.

Furthermore, the Examiner appears to take the position that the periods of incubation are, according to the teachings of U.S. Patent No. 5,851,756, critical.

Applicants respectfully direct the Examiner's attention to MPEP §2164.08(c) which points out that, regardless of what any references disclose or teach, "an enablement rejection based on the grounds that a disclosed critical limitation is missing from a claim should be made only when the language of the specification makes it clear that the limitation is critical for

the invention to function as intended. Broad language in the disclosure, including the abstract, omitting an allegedly critical feature, tends to rebut the argument of criticality."

Here, the subject application, including the abstract, does not require any specific periods of incubation. Contrary to the Office Action, specific periods of incubation are not critical to the claimed invention and therefore are not required to be recited in the claims.

Similarly, although the Office Action does not appear to challenge the sufficiency of the specification for enabling the claimed invention, the Examiner indicated that Applicants must recite in the claims the following features because the features are purportedly essential to the claimed invention: (i) whether adherent cells or nonadherent cells are saved or are discarded; (ii) specific time periods or ranges; (ii) specific reagents used in the incubation; and (iv) specific ratio or range of ratios of microcarrier beads to culture volume.

As pointed out above, the MPEP, which provides the guideline for examination of the application, states that it is the specification, not the claims which sets forth how to practice the claimed invention (MPEP §2164.08). The enablement test looks at whether the specification provides sufficient disclosure to enable one skilled in the art to make and use the claimed invention (see MPEP §2164.01).

Since the application (see the Abstract) does not indicate that any of features (i) through (iv) are critical to the claimed invention, Applicants maintain the features are not required to be recited in the claims. It should also be noted that the Office Action apparently does not deny the sufficiency of the specification.

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Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1-12 under 35 U.S.C. §112, first paragraph.

In view of the amendments to the claims and remarks hereinabove, Applicants maintain that claims 1-12 are now in condition for allowance. Accordingly, Applicants earnestly solicits the allowance of claims 1-12.

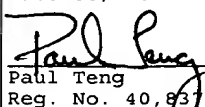
If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the telephone number provided below.

If a petition for an extension of time is required to make this response timely, this paper should be considered to be such a petition, and the Commissioner is authorized to charge the requisite fees to our Deposit Account No. 03-3125.

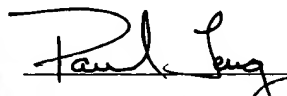
No fee is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being transmitted by facsimile transmission this date and is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Box AF, Washington, D.C. 20231.


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March 31, 2003
Date



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